

PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

| | | |
|--|----|--|
| (51) International Patent Classification 6 : A61B 5/00 | A1 | (11) International Publication Number: WO 00/32097 |
| | | (43) International Publication Date: 8 June 2000 (08.06.00) |
| <p>(21) International Application Number: PCT/US99/28296</p> <p>(22) International Filing Date: 1 December 1999 (01.12.99)</p> <p>(30) Priority Data: 09/203,880 1 December 1998 (01.12.98) US 09/216,012 16 December 1998 (16.12.98) US</p> <p>(71) Applicant: HEALTH HERO NETWORK, INC. [US/US]; Suite 111, 2570 West El Camino Real, Mountain View, CA 94040 (US).</p> <p>(72) Inventor: BROWN, Stephen, J.; 3324 Woodside Road, Woodside, CA 94062 (US).</p> <p>(74) Agent: SMITH, Michael, S.; Black, Lowe & Graham, PLLC, 816 Second Avenue, Seattle, WA 98104 (US).</p> | | (81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG). |
| Published <i>With international search report.</i> | | |
| (54) Title: SYSTEM AND METHOD FOR EXECUTING A TREATMENT REGIMEN | | |
| (57) Abstract | | |
| <p>This invention is a client server computer communication system (100) with feedback to dispense medicine, so that medical personnel can receive feedback from the patient regarding the medical regimen. A medicine dispenser (109) is coupled to a client device (110). The patient enters information in the client device (110) about following the medical regimen. Medical personnel can receive that information at a medical professional device (150), and possibly alter the behavior of the client device (110) or the medicine dispenser (109). The medical personnel monitor compliance, effectiveness of the prescribed medical regimen, present regimen reminders for the patient, and alter the medical regimen in response to feedback from the patient. The client device (110) communicates with the server device (160) to receive information regarding when the patient should take the prescribed medicine. The medicine dispenser (109) dispenses only the dosage of medicine directed by the prescribed medical regimen, and records information from the patient regarding compliance.</p> | | |
| | | |

BEST AVAILABLE COPY

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

| | | | | | | | |
|----|--------------------------|----|---------------------------------------|----|---|----|--------------------------|
| AL | Albania | ES | Spain | LS | Lesotho | SI | Slovenia |
| AM | Armenia | FI | Finland | LT | Lithuania | SK | Slovakia |
| AT | Austria | FR | France | LU | Luxembourg | SN | Senegal |
| AU | Australia | GA | Gabon | LV | Latvia | SZ | Swaziland |
| AZ | Azerbaijan | GB | United Kingdom | MC | Monaco | TD | Chad |
| BA | Bosnia and Herzegovina | GE | Georgia | MD | Republic of Moldova | TG | Togo |
| BB | Barbados | GH | Ghana | MG | Madagascar | TJ | Tajikistan |
| BE | Belgium | GN | Guinea | MK | The former Yugoslav Republic of Macedonia | TM | Turkmenistan |
| BF | Burkina Faso | GR | Greece | ML | Mali | TR | Turkey |
| BG | Bulgaria | HU | Hungary | MN | Mongolia | TT | Trinidad and Tobago |
| BJ | Benin | IE | Ireland | MR | Mauritania | UA | Ukraine |
| BR | Brazil | IL | Israel | MW | Malawi | UG | Uganda |
| BY | Belarus | IS | Iceland | MX | Mexico | US | United States of America |
| CA | Canada | IT | Italy | NE | Niger | UZ | Uzbekistan |
| CF | Central African Republic | JP | Japan | NL | Netherlands | VN | Viet Nam |
| CG | Congo | KE | Kenya | NO | Norway | YU | Yugoslavia |
| CH | Switzerland | KG | Kyrgyzstan | NZ | New Zealand | ZW | Zimbabwe |
| CI | Côte d'Ivoire | KP | Democratic People's Republic of Korea | PL | Poland | | |
| CM | Cameroon | KR | Republic of Korea | PT | Portugal | | |
| CN | China | KZ | Kazakhstan | RO | Romania | | |
| CU | Cuba | LC | Saint Lucia | RU | Russian Federation | | |
| CZ | Czech Republic | LI | Liechtenstein | SD | Sudan | | |
| DE | Germany | LK | Sri Lanka | SE | Sweden | | |
| DK | Denmark | LR | Liberia | SG | Singapore | | |
| EE | Estonia | | | | | | |

SYSTEM AND METHOD FOR EXECUTING A TREATMENT REGIMEN

5.

Background of the Invention

When medical personnel prescribe treatment regimens for patients or "patients" undertake non-prescription treatment regimens (whether such regimens prescribed or undertaken for medication, physical therapy, psychological therapy, self improvement, or other purposes), a problem can arise in assuring that the patients comply with the requirements of the treatment regimen. For example, some patients are disorganized, forgetful, or simply unwilling to comply. When the treatment regimen has potential side effects, or when the treatment regimen is to be followed under stated conditions (for example, taking medication with meals, not with alcohol, or in the evening) patient compliance can be relatively reduced even further. When the treatment regimen is relatively complex, some patients are even unable or unwilling to manage that treatment regimen.

Known methods for monitoring and controlling treatment regimens are relatively costly and limited in capability. Some known methods are described in the following 20 patents:

U.S. Patent 5,408,443, "Programmable Medication Dispensing System", issued April 18, 1995 in the name of Edward D. Weinberger.

U.S. Patent 5,642,731, "Method Of An Apparatus For Monitoring And Management Of Disease", issued July 1, 1997 in the name of Bruce A. Kehr.

U.S. Patent 5,752,235, "Electronic Medication Monitoring And Dispensing Method", issued May 12 1990 in the name of Bruce A. Kehr, et al.

While these known methods generally achieve the goal of monitoring and
5 controlling a treatment regimen, particularly medication regimen, they suffer from
several drawbacks and limitations.

First, there is a need to provide the portable system to monitoring and encourage
compliance, and facilitate data collection, so that patients are restricted as little as
possible regarding their activities and movements.

10 Second, there is a need to determine if patients actually comply with treatment
regimens at times when the patients are relatively remote to client devices for the system.
Known methods do not provide adequate feedback to determine whether patients are
complying with the treatment regimen unless the remain relatively local to client devices.

Third, there is a need to determine whether treatment regimens have the desired
15 and intended effects. Known methods do not provide adequate feedback to determine
whether treatment regimens are effective, or whether patients are suffering any untoward
side effects. Using known methods, medical personnel must generally wait for patients
to comply, or for medical test to show, that prescribed treatment regimens are inadequate
20 or are producing side effects. Similarly, using known methods, patients undertaking
unprescribed treatment regimens generally do not have effective or convenient systems to
monitor and record whether non-prescribed treatment regimens are producing intended
results.

Fourth, there is a need to inform patients to follow treatment regimens,
particularly when patients are forgetful or treatment regimens are complex. Although
25 prior art systems do include reminders to patients, it would be advantageous to tailor
those reminders to patients' actual compliance history (thus, providing fewer reminders
when they are relatively less necessary and more reminders on their relatively more
necessary).

Fifth, there is a need to leverage expert knowledge to improve response to feedback from patients, and to reduce the time and expense required for medical personnel to individually monitor, evaluate and modify treatment regimens.

Sixth, there is a need to broaden application of reminder and expert knowledge 5 leveraging systems beyond medication regimens, to include physical, psychological, self-improvement and other treatment regimens.

Accordingly, it would be advantageous to provide a portable device that can be coupled and uncoupled to a communication system with feedback to monitor patient compliance, and effectiveness of, treatment regimens, so that input from patients 10 regarding treatment regimens can be recorded, reviewed, analyzed and otherwise generally acted upon. Medical personnel and/or patients can thus (1) monitor compliance with treatment regimens, (2) monitor effectiveness or side effects of treatment regimens, (3) remind patients no more than necessary, and (4) possibly alter treatment regimens in response to feedback from patients. These advantages are achieved in embodiments of 15 the invention in which the portable device is intermittently coupled to a client device in a client-server system, the patient enters information to the portable device about following the treatment regimen while the portable device is uncoupled, and medical personnel or the patient can receive that information and possibly alter the behavior of the portable device when the portable device is recoupled to the system. It would also be 20 advantageous to provide a computer communication system with feedback to dispense medicine, so that medical personnel can receive feedback from the patient regarding the medical regimen.. These advantages are achieved in embodiments of the invention in which a medicine dispenser is coupled to a client device in a client-server system, the patient enters information to the client device about following the medical regimen, and 25 medical personnel can receive that information and possibly alter the behavior of the client device or the medicine dispenser.

Summary of the Invention

The invention provides a method system for interaction with a community of 30 individuals, relating to compliance with and effectiveness of treatment regimens,

including supply and use of pharmaceuticals, using a protocol or other intelligent message which acts in place of a service provider and which is capable of collecting or imparting information to patients in place thereof. Individuals interact with the protocol or intelligent message to provide assistance in all aspects of treatment regimen
5 compliance, data collection, supply or delivery, review and modification. These aspects can include (1) reminders regarding compliance with the selected treatment regimen for medication, physical therapy, psychological therapy, self-improvement, or some combination thereof; (2) data collection of facts regarding patient compliance, symptomology, possible drug interactions or side effects of medication if required by the
10 treatment regimen, and other facts relevant to evaluation and possible modification of the treatment regimen; (3) network integration with workstations for medical professionals to automate approvals and modifications, and refills and delivery of medication if required by the treatment regimen.

A system includes a set of client devices and a server device. A service provider
15 determines the treatment regimen for selected patients, determines a protocol to be followed by the client devices to assist the patient in complying with that treatment regimen [in assisting with that medication regimen] and to maximize effectiveness of treatment, and sends that protocol to the server device. The server device can update (responsive to the protocol) selected instructions at the client devices, and can receive
20 (responsive to selected instructions) information from the client devices regarding their associated patients.

In a first preferred embodiment, a client device, located locally to a patient, couples to a portable device, such as a cellular telephone, pager, Palm pilot or other hand-held computer, or watch, capable of being carried away by the patient to locations
25 relatively remote from client device. The client device can interact with the portable device: (1) to provide the portable device with capability of reminding the patient regarding the treatment regimen; or (2) to provide the portable device with the capability of further data collection regarding patient. The client device can interact with the portable device using a docking connection, and infrared connection, a radio-frequency
30 connection, a plug-in connection, or another suitable connection

Brief Description Of The Drawings

FIGURE 1 shows a block diagram of a medical appliance system formed in accordance with the present invention;

5 FIGURE 2 is a block diagram of a first preferred embodiment of a portable device formed in accordance with the present invention;

FIGURE 3 is a flow diagram for operating the system illustrated in FIGURES 1 and 2;

10 FIGURE 4 shows a first embodiment of a controlled medication dispenser formed in accordance with the present invention;

FIGURE 5 shows a second embodiment of a controlled medication dispenser formed in accordance with the present invention;

FIGURE 6 shows a third embodiment of a controlled medication dispenser formed in accordance with the present invention;

15 FIGURE 7 shows a fourth embodiment of a controlled medication dispenser formed in accordance with the present invention;

FIGURE 8 shows a fifth embodiment of a controlled medication dispenser formed in accordance with the present invention;

20 FIGURE 9 shows a sixth embodiment of a controlled medication dispenser formed in accordance with the present invention;

FIGURE 10 shows a seventh embodiment of a controlled medication dispenser formed in accordance with the present invention; and

FIGURE 11 shows a method for performing the invention as described in FIGURES 4-10.

25 Detailed Description Of Preferred Embodiment

In the following description, a preferred embodiment of the invention is described with regard to preferred process steps and data structures. Embodiments of the invention can be implemented using general purpose processors or special purpose processors operating under program control, or other circuits, adapted to particular process steps and

data structures described herein. Implementation of the process steps and data structures described herein would not require undue experimentation or further invention.

System Elements

5 FIGURE 1 shows a block diagram of the system 100 to encourage and monitor compliance with a treatment regimen using a protocol or other intelligent message, which acts in place of a service provider to collect and impart information relevant to the treatment regimen. System 100 includes a patient device 110, a pharmacist device 140; a medical professional device 150, and a server device 160. The devices are coupled using
10 a communication network 130. A portable device 112 is coupled to the patient device 110 to receive information regarding the treatment regimen and send feedback from the patient 111 responsive thereto. Also, a medication dispenser 109 is coupled to the portable device 112 or the patient device 110.

FIGURE 2 shows the preferred embodiment of the portable device 112 used by
15 the system 100. In a first preferred embodiment, the portable device 112 and medication dispenser 109 has its own power source 119 and includes a coupling element 113 for coupling the portable device 112 to the patient device 110, a memory device 114, a processor chip 115 including a clock circuit 116, a presentation element 117, and a patient feedback input element 118. A service provider determines a treatment regimen
20 for selected patients 111 and a protocol to be followed by their portable devices 112 to assist the patients 111 in following the treatment regimen. The service provider sends the treatment regimen and protocol to the server device 160 where it is recorded in the database 161. The server device 160 sends the treatment regimen and protocol information to the patient device 110, and optionally to the pharmacist device 140 and the
25 medical professional device 150. The portable device 112 is coupled to the patient device 110 using the coupling element 113. The coupling element 113 may couple using a docking station, an infrared connection, a radio-frequency connection, a plug-in connection, other suitable means or any variance thereof.

While coupled, the treatment regimen and protocol information received by the
30 patient device 110 is sent to the portable device 112 and recorded in the memory 114. In

a first preferred embodiment, the power source 119 is rechargeable and the charge can be replenished by the patient device 110 while the portable device 112 is coupled to it. In alternative embodiments, the power source 119 is rechargeable and the charge can be replenished by some other device, or includes one or more disposable batteries.

- 5 After the treatment regimen and protocol information is recorded in the memory 114, the portable device 112 can be uncoupled from the patient device 110 and taken with the patient 110 to locations relatively or logically remote from the patient device 110. Whether the portable device 112 coupled or uncoupled to the patient device 110, when the patient 111 is due to perform an act according to treatment regimen,
- 10 the portable device 112 uses a presentation element 117 to provide a reminder message instructing the patient 111 to perform that act. In a first preferred embodiment, the act to be performed is related to compliance with a medication regimen including, without limitation, obtaining medicine, taking medicine, taking medicine with another substance such as food or water, not taking medicine with another substance such as alcohol or
- 15 incompatible medications, or obtaining a prescription refill. In alternative embodiments the act to be performed may be pursuant to a physical therapy regimen including, without limitation, exercising, stretching, changing position, or changing work routine; pursuant to a psychological therapy regimen including, without limitation, repeating an affirmation, meditation, self-hypnosis or other mental activity; or pursuant to a self-help
- 20 regimen or other type of treatment regimen such as weight loss including, without limitation, drinking water or eating a snack.

- The patient 111 performs the indicated act and enters a message into the portable device 112 confirming performance of the act using the patient feedback input element 118. Operation of the patient feedback input element 118 causes the processor chip 115 to cancel the reminder message, check the clock 116, and recorded the time and fact of performance in the memory 114. In a first preferred embodiment, the patient 111 also enters additional information relevant to monitoring and evaluating the treatment regimen in response to queries by the presentation element 117 in accordance with the treatment regimen and protocol.

- The number of reminder messages provided to the patient 111, and the number of messages from the patient 111 confirming performance of the indicated acts and/or providing other information relevant to compliance with and effectiveness of the treatment regimen, is limited only by the memory capacity of the portable device 112. In
- 5 a first preferred embodiment, the presentation element 117 is a human readable visual display using LCD's, LCD's, or other suitable devices. In alternative preferred embodiments, the presentation element 117 can be a device, which produces human-intelligible sound, or a combination of devices, which produce human-intelligible visual and audible signals.
- 10 At some later time, the portable device 112 is re-coupled to the patient device 110 using the coupling element 113, causing the contents of the memory 114 to be downloaded into the patient device 110 and sent to the server device 160 for recording in the database 161. Such a time may be as is convenient to the patient 111, or according to a selected maximum time interval dictated by the treatment regimen and protocol, or as is
- 15 required to replenish the power source 119 of the portable device 112, or in accordance with other requirements of the system 100.
- At the server device 160, the protocol or other intelligent message reviews and compares the information provided by the patient 111 to the requirements of the treatment regimen in order to evaluate the effectiveness of the treatment regimen toward
- 20 achieving treatments objectives and as to compliance of the patient 111 with the treatment regimen. The protocol may then leave the treatment regimen unchanged or modify it as needed to increase effectiveness and/or compliance; in either case, the server device 160 sends a message to the patient device 110 as to the regimen to be followed from the that time forward. In a preferred embodiment, the server device 160 also sends
- 25 that message to the pharmacist device 140 and the medical professional device 150.
- In a first preferred embodiment, information regarding the entire course of the treatment regimen, such as each updated regimen and its effectiveness and relative compliance by the patient can be stored by each of those devices and displayed on demand. In alternative embodiments, only the server records the entire course, or only
- 30 selected devices, or some combination thereof.

In a preferred embodiment, when a treatment regimen requires a patient 111 to take one or more medications, the portable device 112 is coupled to the medication dispenser 109 containing medication specified by the treatment regimen. In an alternative embodiment, the portable device 112 also controls the medication dispenser 109 so as to release only the correct dosage of the correct medication at the correct time responsive to the treatment regimen. In a further alternative preferred embodiment, the dispenser 109 automatically provides feedback to the portable device 112 when the correct medication is removed, canceling the reminder message and storing the feedback for subsequent downloading to the patient device 110 on the next occasion that the portable device 112 is coupled to the patient device 110.

The patient device 110 can be any device for electronic communication including, but not limited to, and application specific device, a hard-wired telephone, a cellular telephone, a pager, the personal desktop computer, a personal notebook computer, a hand-held computing device, and Internet appliance, an Internet-enabled television such as WebTV, personal digital assistants such as the Palm III, or any variant thereof.

The portable device 112 can be any portable device for electronic communication which is capable of being coupled to the patient device 110 including, without limitation, an application specific device, a cellular telephone, a pager, a personal notebook computer, a hand-held computing device, an Internet appliance, a personal digital assistant such as the Palm III, a watch, or any variant thereof. The feedback input element 118 can be any means of providing input to an electric communication device including, but not limited to, a button, a telephone key, a computer keyboard key, a voice-response activator, or any variant or combination thereof.

25

Method Of Operation

FIGURE 3 shows a process flow diagram of a method for operating a system for leveraging expert interaction with a community of individuals to encourage compliance with a treatment regimen and for collecting and imparting information relevant to treatment regimen.

A method 200 is performed by the system 100, as follows. At a flow point 201, the system 100 is ready to proceed. At a step 202, the service provider enters information concerning a treatment regimen and protocol to be followed by the patient 111. At a step 203, the treatment regimen and protocol information is sent to the server device 160

5 using the communications network 130. At a step 204, the server device 160 records the treatment regimen and protocol information received from the service provider in the database 161. At a step 205 in a preferred embodiment, the server device 160 sends treatment regimen and protocol information to the patient device 110, the pharmacist device 140 and the medical professional device 150 using the communication

10 network 130. In alternative embodiments, the server device 160 may send the treatment regimen and protocol information only to the patient device 110. At a step 206, the portable device 112 is coupled to the patient device 110 and the treatment regimen and protocol information is copied into the memory 114 of the portable device 112. At a step 207, the portable device 112 is uncoupled from the patient device 110 and is taken

15 with the patient 111 to a location relatively remote patient device 110.

At a step 208, responsive to treatment regimen and protocol information stored in the memory 114 in conjunction with input from the clock 116, the patient device 110 uses the presentation element 117 to provide a reminder message to the patient 111 that an act is required to be performed by the patient 111 and instructs the patient 111 regarding the

20 act to be performed. At a step 209, the patient 111 performs the indicated act as directed. At a step 210, the patient 111 operates the feedback input element 118 on the portable device 112, canceling the reminder message. At a step 211, the portable device 112 uses the presentation element 117 to query the patient 111 to provide information responsive to the protocol for evaluating the effectiveness of the treatment regimen. At a step 212,

25 the patient 111 operates of the feedback input element 117 to provide information responsive to the queries, and that information is recorded in the memory 114.

At a step 213, the portable device 112 is re-coupled to patient device 110. At a step 214, the information stored in the memory 114 is sent to the patient device 110, which in turn sends that information to the server device 160 using the communication

30 network 130. At a step 215, the information received by the server device 160 is

recorded in the database 161. At a step 216, in the preferred embodiment the server device 160 sends the information received from the patient device 110 to the pharmacist device 140 and to the medical professional device 150 using the communication network 130. In an alternate embodiment, the server device 160 does not send the 5 information received from the patient device 110 to the pharmacist device 140 or to the medical professional device 150, whether using the communication network 130 or otherwise. At the step 217, the information received by the server device 160 from the patient device 110 is evaluated by the protocol. At a step 218, the protocol updates the treatment regimen and either leaves it unchanged or modifies it in accordance with 10 protocol logic. At a step 219 in the preferred embodiment, the server device 160 sends the updated treatment regimen information to the patient device 110, to the pharmacist device 140 and to the medical professional device 150, using the communications network 130. In an alternative embodiment, the server device 160 does not send the updated treatment regimen information to the pharmacist device 140 or the medical 15 professional device 150.

At a step 220 in a preferred embodiment, the pharmacist 141 and/or the medical professional 151 review and compare the original treatment regimen, the compliance and other information input by the patient 111, and the updated treatment regimen, and either leave the updated treatment regimen and protocol information unchanged or modify it as 20 necessary. In an alternative embodiment, step 220 does not take place. At a step 221 in a preferred embodiment, the treatment regimen and protocol information as unchanged or as modified by the pharmacist 141 and/or the medical professional 151 is sent to the server device 160 using the communication network 130. In an alternative embodiment, step 221 does not take place. At a step 222, the server device 160 records the treatment 25 regimen and protocol information as unchanged or as modified by the pharmacist 141 and/or the medical professional 151 in the database 161. In an alternative embodiment, step 222 does not take place.

At a step 223 in a preferred embodiment, the server device 160 sends the treatment regimen and protocol information as unchanged or as modified by the 30 pharmacist 141 and/or the medical professional 151 to the patient device 110 using the

communication network 130. In an alternative embodiment, step 223 does not take place. At a step 224, the patient device 110 sends the updated treatment regimen information to portable device 112 and it is recorded in the memory 114. At a step 225, the patient device 110 replenishes the charge of the power source 119. At a step 226, the patient 111 uncouples the portable device 112 from the patient device 110. At a step 227, the pharmacist 141 provides a refill or new medicine to the patient 111 responsive to the treatment regimen and protocol information. In an alternative embodiment, step 227 does not take place.

10

Medication Dispenser

With Identifying Letter Or Symbol On Or Immediately Adjacent To Compartment

FIGURE 4 shows a first embodiment of the controlled medication dispenser 109 used by the system 100. The medication dispenser 109 includes one or more medication compartments 313. Each medication compartment 313 is labeled with a human-readable identifying letter or symbol 314 on or immediately adjacent to the medication compartment 313. The medication compartment 313 are filled with medication by the pharmacist 141, the medical professional 150, the patient 111 or other supplier. The pharmacist 141 enters medication regimen information regarding the patient 111 into the pharmacist device 140 which sends it to the server device 160 where it is recorded in the database 161. The server device 160 then sends the medication regimen information to the patient device 110 and optionally to the medical professional device 150.

When the patient 111 is due to take a medication according to the medication regimen, the patient device 110 sends a reminder message to the patient 111 indicating that a medication is to be taken, indicating the letter or identifying symbol 314 of the medication compartment 313 containing the medication to be taken, and indicating the dosage of medication to be taken. The patient 111 then manually opens the indicated medication compartment 313 and takes the indicated dosage of the medication contained there. After taking the medication, the patient 111 enters a message that the medication has been taken into the patient device 110 using a signifying device 324, shown in FIGURE 8, which cancels the reminder message and sends the message that the

medication has been taken to the server device 160 where it is recorded in the database 160. The server device 160 then sends the message that the medication has been taken to the pharmacist device 140 and optionally to the medical professional device 150.

In this first embodiment the medication dispenser 109 is not directly coupled to the patient device 110 and is controlled entirely by the patient 111. The patient device 110 can be any device for electronic communication including, but not limited to, an application specific device, a hard-wired telephone, a cellular telephone, a pager, a personal desktop computer, a personal notebook computer, a hand-held computing device, an internet appliance, an internet-enabled television, such as Web TV, or personal digital assistant, such as the Palm III. The signifying device 324 can be any means of providing input to an electronic communication device including, but not limited to, a button, a telephone key, a computer keyboard key, or a voice-response activator.

With Unique Identifying Device

FIGURE 5 shows a second embodiment of the controlled medication dispenser 109 used by the system 100. The medication dispenser 109, as in the first embodiment and also including a unique identifying device 316, either as part of the medication dispenser 109 itself or as part of a module attached to the medication dispenser 109. The unique identifying device 316 provides positive identification of the medication dispenser 109 to the patient device 110 to reduce the risk of error when dispensing medication to the patient 111. The unique identifying device 316 can be any device capable of providing positive identification including, but not limited to, a smart card.

With Unique Identifying Device And LED Adjacent To Compartment

FIGURE 6 shows a third embodiment of the controlled medication dispenser 109 used by the system 100. The medication dispenser 109 is similar to the second embodiment but without the identifying letter or symbol 314 but including a LED or equivalent 317 located on or immediately adjacent to each medication compartment 313. When the patient 111 is due to take a medication according to the medication regimen, the medication compartment 313 containing the medication to be taken is identified

responsive to the patient device 110 or the portable device 112, see FIGURE 8 below, by illumination of the LED 317.

With Unique Identifying Device And Single Digit Display Adjacent To Compartment

5 FIGURE 7 shows a fourth embodiment of the controlled medication dispenser 109 used by the system 100. The medication dispenser 109 as in the third embodiment but with the LED 317 replaced by a single digit display 318 that is located on or immediately adjacent to each medication compartment 313. When the patient 111 is due to take a medication according to the medication regimen, the medication 10 compartment 313 containing the medication to be taken is identified responsive to the patient device 110 by illumination of the single digit display 318, which also indicates the number of medications to be taken from that medication compartment 313.

With Unique Identifying Device And Portable Module Including Signifying Device

15 FIGURE 8 shows a fifth embodiment of the controlled medication dispenser 109 used by the system 100. The medication dispenser 109 as in the third embodiment is made portable by connection to the portable device 112. The portable device 112 is programmed with the medication regimen information by the patient device 110, the pharmacist device 140, or the medical professional device 150, to which the portable 20 device is connected as necessary. Times when a medication is to be taken by the patient 111 according to the medication regimen are identified by the clock 116 and the processor chip 115. The processor chip 115 then causes the LED 317, that is located on or immediately adjacent to the medication compartment 313 containing the medication to be taken, to be illuminated. In an alternative embodiment, the processor chip 115 also 25 causes an audible warning device to produce a sound, which can be heard by the patient 111.

After taking the indicated medication dosage the patient 111 operates the signifying device 324, cancelling illumination of the LED 317 and production of sound by the audible warning device, and further causing the portable device 112 to record the 30 time at which the patient 111 operated the signifying device 324 for downloading to the

patient device 112, the pharmacist device 140 or the medical professional device 150 the next time the patient device 112 is connected to such device.

*With Unique Identifying Device And Portable Module Including
5 Signifying Device And Single Digit Display*

FIGURE 9 shows a sixth embodiment of the controlled medication dispenser 109 used by the system 100. The medication dispenser 109 as in the fifth embodiment, and also including a single digit display 325 located on the portable device 112 attached to the medication dispenser 109. When a medication is due to be taken, the processor chip 115 causes the single digit display 325 to illuminate and display a number indicating the number of medications to be taken from the compartment 313 identified by the LED 317.

*15 With Unique Identifying Device And Portable Module Including
Signifying Device And Two Digit Display*

FIGURE 10 shows a seventh embodiment of the controlled medication dispenser 109 used by the system 100. In the seventh embodiment, the medication dispenser 109 as in the second embodiment, and also including a portable device 112 as in the fifth embodiment but with the single digit display 325 replaced by a two digit display 326 located on the portable device 112 attached to the medication dispenser 109. When a medication is due to be taken, the processor chip 115 causes the two digit display 326 to illuminate and display both the identifying letter or symbol of the medication compartment 313 containing the medication to be taken, as well as to display a number indicating the number of medications to be taken from the compartment 313. In an alternative embodiment, two single digit displays are included in the portable device 112 rather than a single two-digit display.

With Enhanced Unique Identifying Device

In an eighth embodiment, the unique identifying device 316 is a smart card or 30 equivalent into which the pharmacist 141 can enter additional information such as the

name of the patient 111, names of medications, location of medications in the medication compartments 313, dosage of medications, timing of dosages, etc., and such additional information can be read from the smart card or equivalent by the patient device 110, by the medical professional 151 with an attachment 152 to the medical professional device 150, or by the portable device 112.

With Portable Device, Unique Identifying Device, And Enhanced Processor Chip

In a ninth embodiment, the portable device 112 includes an enhanced processor chip which can interpret medication regimen information recorded in the unique identifying device 316 such as timing and amount of dosage, and which can operate independently of the patient device 110 to provide through the portable device 112 a reminder message indicating that a dosage is to be taken.

Method of Operation

15 FIGURE 11 shows a process flow diagram of a method for communication with feedback to dispense medicine. A method 400 is performed by the system 100, including the patient device 110, the pharmacist device 140, the medical professional device 150, and the server device 160.

First at flow point 401, the system 100 is ready to proceed. At a step 402, the 20 medication dispenser 109 is filled with one or more medications by the pharmacist 141 or the patient 111. At a step 403, the pharmacist 141 enters into the pharmacist device 140 information concerning the medication regimen to be followed by the patient 111. In a preferred embodiment, such medication regimen information includes type of medication, timing of dosage, quantity of dosage, and identification of compartments 313 25 in the medication dispenser 109. At a step 404, the pharmacist device 140 sends the medication regimen information to the server device 160 using the communications network 130.

At a step 405, the server device 160 records the medication regimen information received from the pharmacist device 140 in the database 161. At a step 406 in a preferred 30 embodiment, the server device 160 sends the medication regimen information to the

patient device 110 and to the medical professional device 150 using the communication network 130. In an alternative embodiment, the server device 160 sends the medication regimen information only to the patient device 110. At a step 407, responsive to the medication regimen information, the patient device 110 provides a warning message to 5 the patient 111 when a medication is to be taken and also instructs the patient 111 regarding which compartment 313 in the medication dispenser 109 contains the medication and what dosage of that medication is to be taken.

At a step 408, the patient 111 removes the dosage of medication to be taken from the indicated compartment 313 and takes the medication as directed. In a preferred 10 embodiment the patient communication device 110 controls the medication dispenser 112 so as to allow only the correct compartment 313 to open and so as to dispense only the correct dosage of medication. At a step 409, the patient 111 operates the signaling device 124 on the patient device 110 canceling the warning message to the patient and sending to the server device 160 a message that the medication has been taken by using 15 the communication network 130. At a step 410, the server device 160 records in database 161 the message received from the patient device 110 that the medication has been taken.

At a step 411, the server device 160 sends the message received from the patient device 110 that the medication has been taken to the pharmacist device 140 using 20 communication network 130. At a step 412 in a preferred embodiment, the server device 160 also sends the message received from the patient device 110 that the medication has been taken to the medical professional device 150 using the communication network 130. In an alternative embodiment, the server device 160 does not send the message received from the patient device 110 that the medication has been 25 taken to the medical professional device 150, either using the communication network 130 or otherwise. At a step 413 in a preferred embodiment, the medical professional 151 reviews the medication regimen information received from the pharmacist device 140 and compares it to the message received from the patient device 110 that the medication has been taken. In an alternative embodiment, the 30 medical professional 151 does not review the medication regimen information received

from the pharmacist device 140 and does not compare it to the message received from the patient device 110, either using the communication network 130 or otherwise.

At a step 414 in a preferred embodiment, the medical professional 151 enters feedback regarding the compliance of the patient 100 with the medication regimen into 5 the medical professional device 150. In an alternative embodiment the medical professional 151 does not provide feedback. At a step 415 in a preferred embodiment, the medical professional device 150 sends the feedback to the server device 160 using the communication network 130. In an alternative embodiment the medical professional device does not send feedback to the server device 160. At a step 416 in a preferred 10 embodiment, the server device 160 records the feedback received from the medical professional device 150 in the database 161. In an alternative embodiment the server device 160 does not record feedback from the medical professional device 150.

At step 417 in a preferred embodiment, the server device 160 sends the feedback received from the medical professional device 150 to the patient device 110 and to the 15 pharmacist device 140 using the communication network 130. In an alternative embodiment the server device 160 does not send feedback to the patient device 110 or the pharmacist device 140. At a step 418 in a preferred embodiment, the pharmacist 141 enters amended medication regimen information into the pharmacist device 140 responsive to the feedback received from the medical professional device 150. In an 20 alternative embodiment the pharmacist 141 does not amend the medication regimen responsive to feedback from the medical professional device 150. At a step 419 in a preferred embodiment, the pharmacist device 140 sends the amended medication regimen information to the server device 160 using the communication network 130. In an alternative embodiment the pharmacist device 140 does not send amended medication 25 regimen information to the server device 160.

At a step 420 in a preferred embodiment, the server device 160 records the amended medication regimen information in the database 161. In an alternative embodiment the server device 160 does not record amended medication regimen information in the database 161. At a step 421 in a preferred embodiment, the server 30 device 160 sends the amended medication regimen information to the patient device 110

and to the medical professional device 150 using the communication network 130. In an alternative embodiment the server device 160 does not send amended medication regimen information to the patient device 110 and to the medical professional device 150.

5

Alternative Embodiments

Although preferred embodiments are disclosed herein, many variations are possible which remain within the concept, scope, and spirit of the invention, and these variations would become clear to those skilled in the art after perusal of this application.

Claims

1. A method of encouraging patient compliance with a treatment regimen, said method comprising:
 - 5 providing first information about said treatment regimen to a server device in a client-server system;
 - sending said first information to a portable proxy device for a client device in said client-server system;
 - receiving second information from said patient at said portable proxy device regarding compliance with said treatment regimen;
 - 10 sending said second information from said portable proxy device to said server device; and
 - comparing said first information with said second information.
- 15 2. The method of Claim 1, further comprising altering a sequence of processing steps at said portable proxy device in response to said server device.
3. The method of Claim 1, further comprising altering a sequence of processing steps at said portable proxy device in response to a result from comparing.
- 20 4. The method of Claim 1, further comprising controlling a medicine dispenser coupled to said client device in response to said second information.
5. The method of Claim 1, wherein said medicine dispenser is coupled to said portable proxy.
- 25 6. The method of Claims 4 or 5, further comprising presenting a reminder at said medicine dispenser regarding following said treatment regimen.

7. The method of Claims 4 or 5, further comprising receiving third information at said client device regarding an effect of medication from said medical dispenser.

5 8 The method of Claim 7, further comprising altering said first information in response to said third information.

9 The method of Claim 1, further comprising presenting a result of said comparing said first information with said second information to an operator at said 10 server device.

10. The method of Claim 1, further comprising presenting a reminder at said portable proxy device regarding following said treatment regimen.

15 11. The method of Claim 10, further comprising receiving third information at said portable proxy device regarding an effect of an act performed responsive to said treatment regimen.

12. The method of Claim 11, wherein said third information relates to an 20 effect of medicine taken by said patient responsive to said reminder.

13. The method of Claim 11, further comprising altering said first information in response to said third information.

25 14. A client-server system for encouraging patient compliance with a treatment regimen, said system comprising:

a server device for receiving first information about a treatment regimen;
and

30 a client device for receiving said first information from said server device and performing processing steps according to said received first information, said client

device comprises a portable proxy device for performing one or more of said processing steps and receiving second information from a patient regarding said performed processing steps;

5 wherein said portable proxy device sends said second information to said server device and said server device compares said first information to said second information.

15. The system of Claim 14, wherein said server device alters said first information for altering the processing steps performed by said portable proxy device.

10

16. The system of Claim 15, wherein said server device alters said first information in response to said comparison.

15

17. The system of Claim 14, further comprising a medicine dispenser coupled to said portable proxy device, said client device wherein controls said medicine dispenser according to said second information.

20

18. The system of Claim 14, further comprising a medicine dispenser coupled to said client device, wherein said client device controls said medicine dispenser according to said second information.

19. The system of Claims 17 or 18, wherein said medicine dispenser comprises an indicator for reminding the patient regarding said treatment regimen.

25

20. The system of Claims 17 or 18, wherein said medical dispenser generates third information regarding an effect of medication.

21. The system of Claim 20, wherein said server device alters said first information in response to said third information.

30

22. The system of Claim 14, wherein said server device presents a result of comparing said first information with said second information to an operator.

23. The system of Claim 14, wherein said portable proxy device presents a reminder regarding following said treatment regimen.

24. The system of Claim 23, wherein said portable proxy device generates third information regarding an effect of an act performed responsive to said treatment regimen.

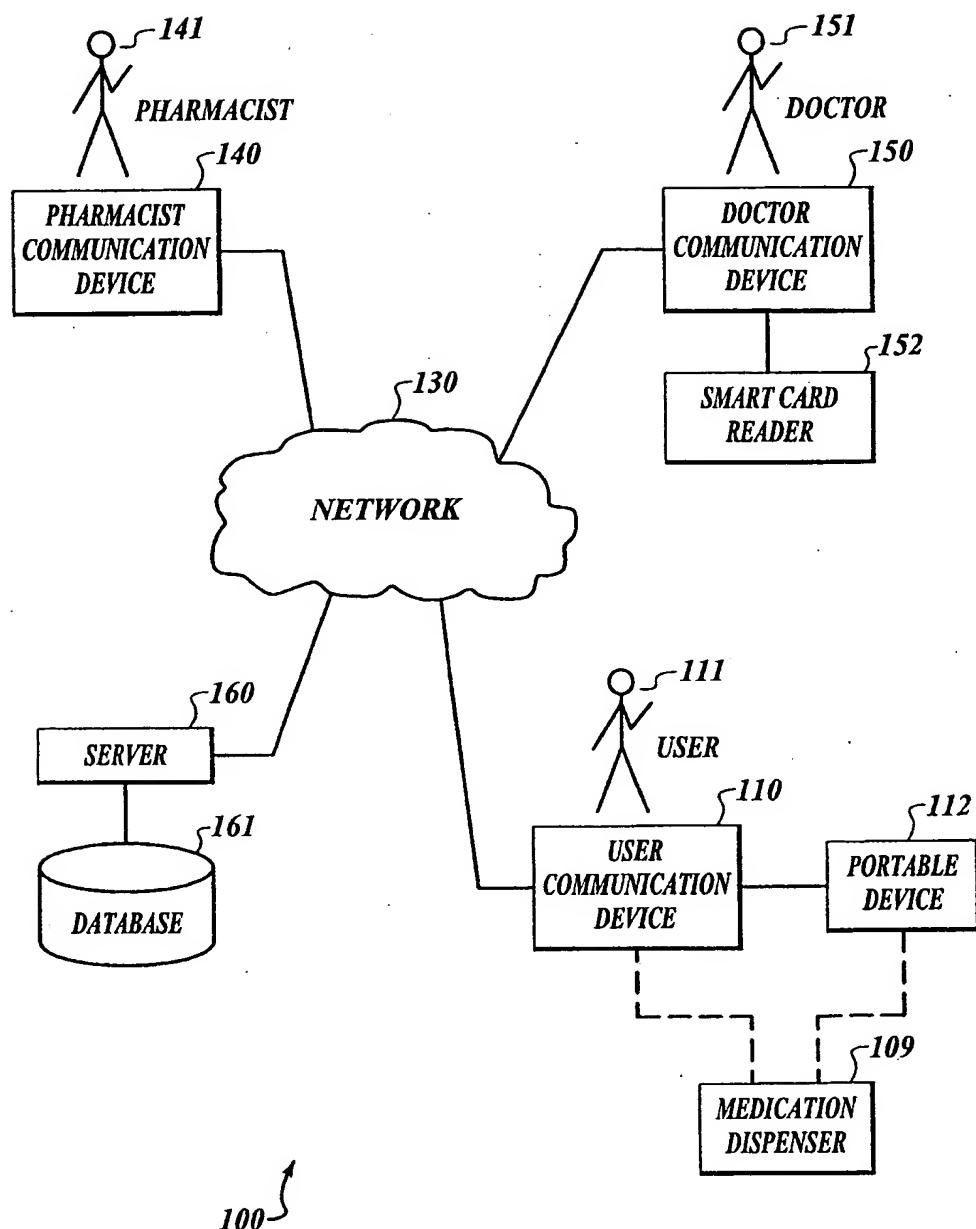
10

25. The system of Claim 23, wherein said third information relates to an effect of medicine taken by said patient responsive to said reminder.

15

26. The system of Claim 23, further comprising altering said first information in response to said third information.

1/7

*Fig. 1*

2/7

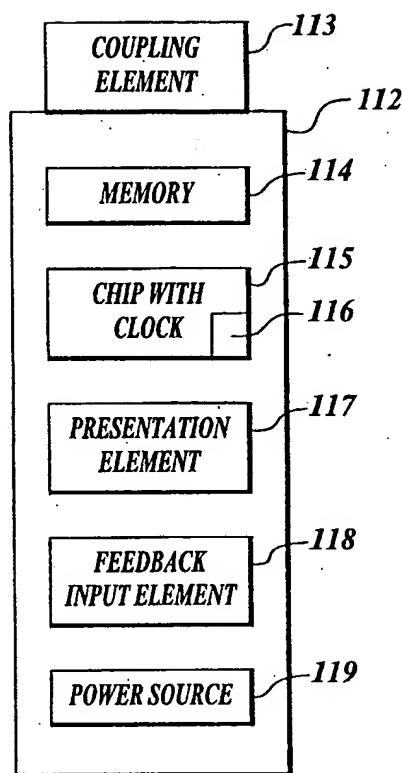
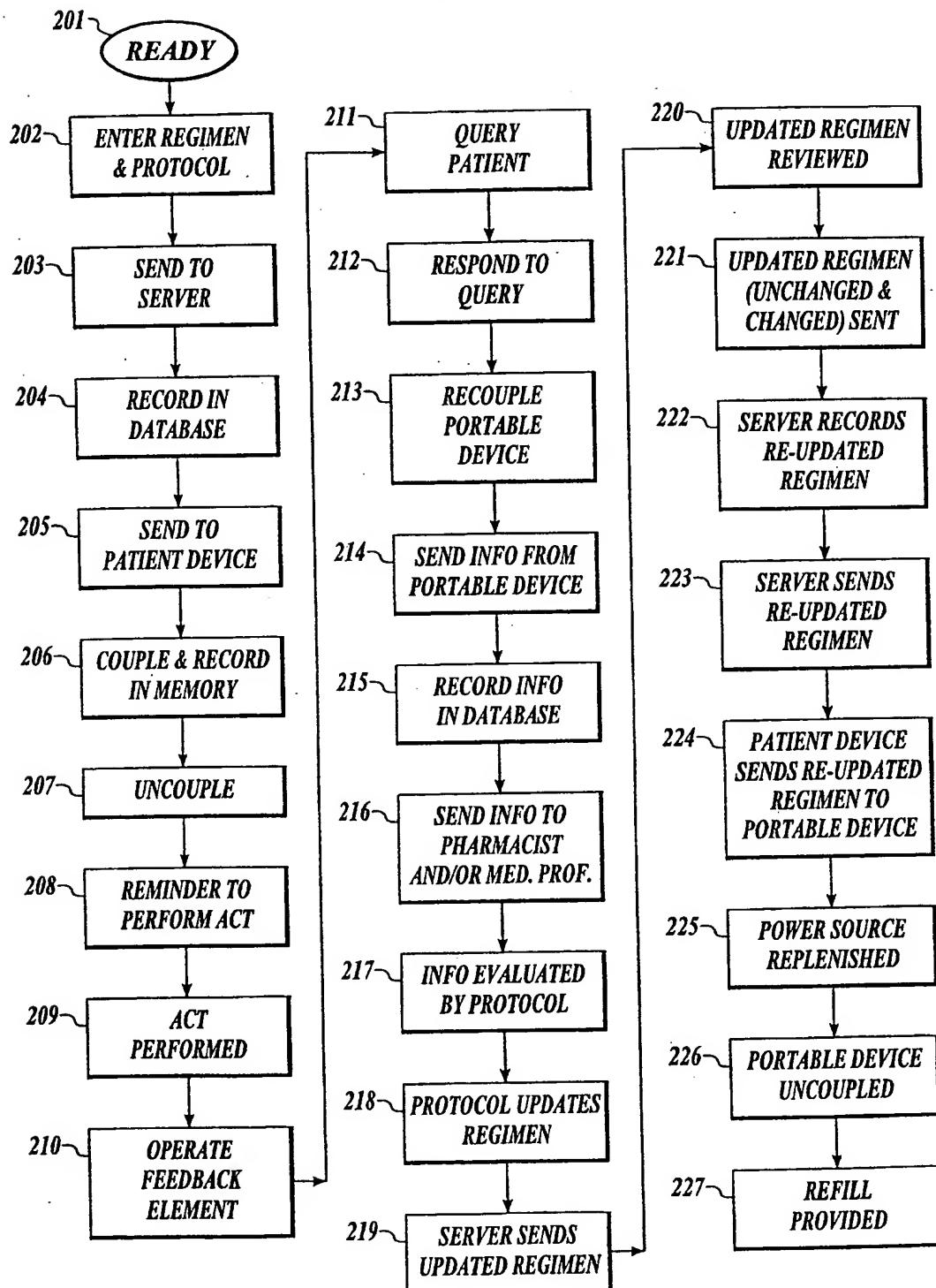


Fig.2

3/7



200 ↗

Fig.3

4/7

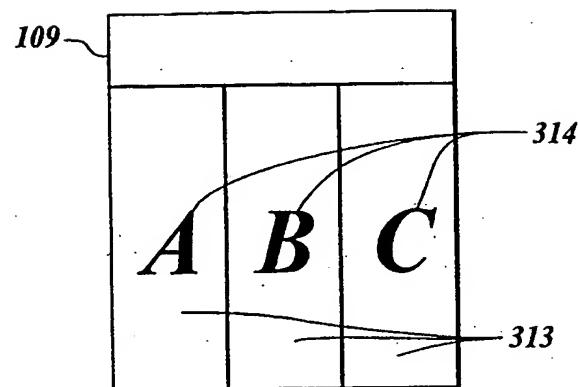


Fig.4

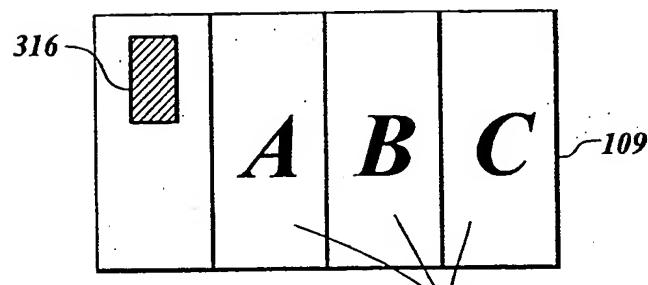


Fig.5

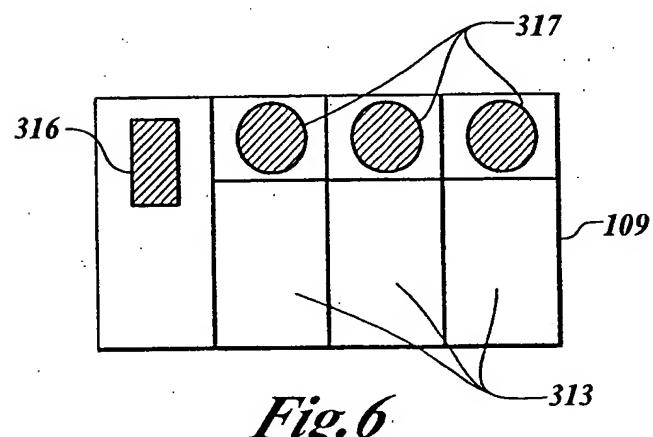
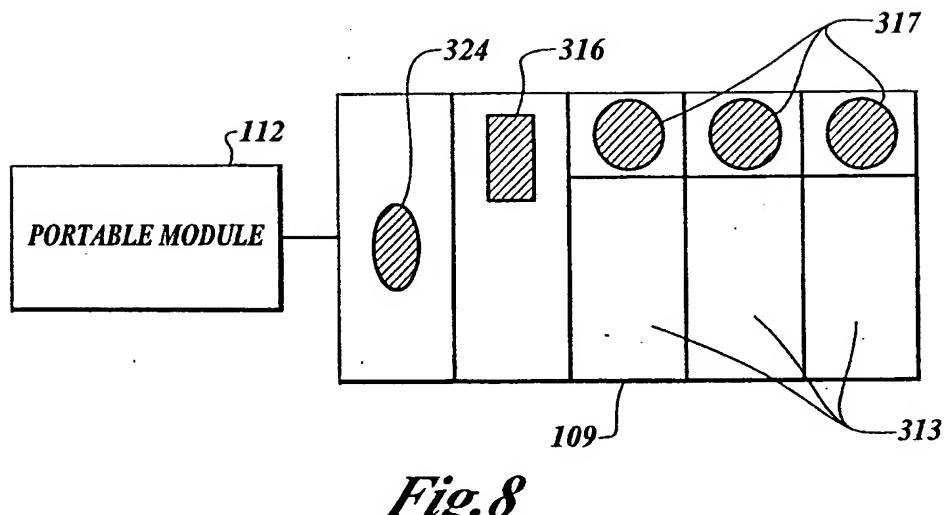
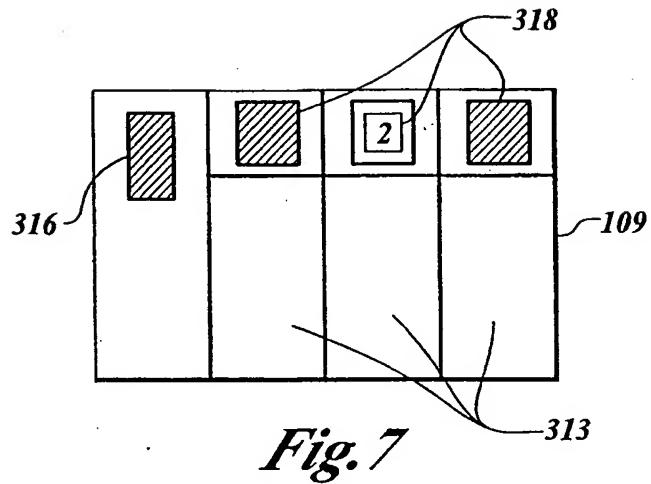
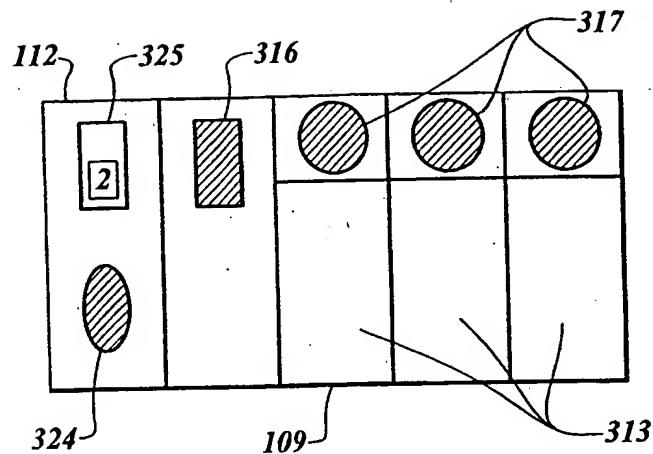
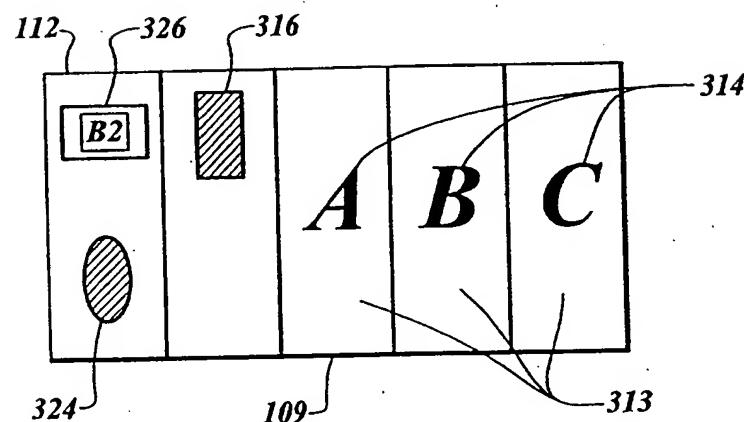


Fig.6

5/7



6/7

*Fig. 9**Fig. 10*

7/7

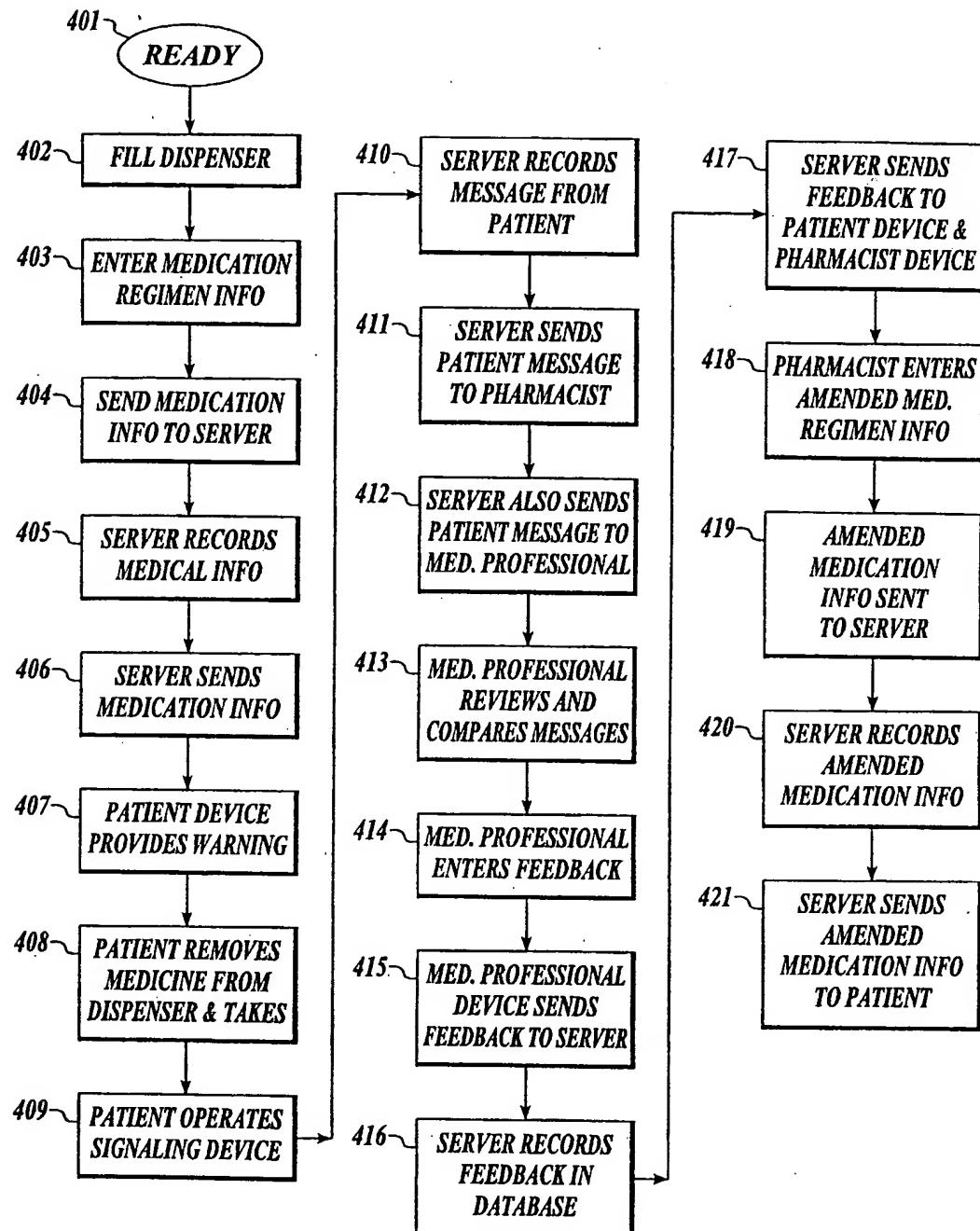


Fig.11

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US99/28296

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : A61B 5/00

US CL : 600/300

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 600/300; 705/2, 3

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EAST

Search Terms: medical treatment, regimen, compliance, medicine, dispenser, monitor, client, server, network

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|-----------|--|-----------------------|
| X | US 5,390238 A (KIRK et al.) 14 February 1995, col. 2 line 56 to col. 6 line 16. | 1-26 |
| A | US 5,827,180 A (GOODMAN) 27 October 1998, entire document. | 1-26 |
| A | US 5,646,912 A (COUSIN) 08 July 1997, entire document. | 1-26 |
| A | US 5,752,235 A (KEHR et al.) 12 May 1998, entire document. | 1-26 |

 Further documents are listed in the continuation of Box C. See patent family annex.

| | | |
|---|-----|--|
| * Special categories of cited documents: | T | later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention |
| "A" document defining the general state of the art which is not considered to be of particular relevance | "X" | document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone |
| "E" earlier document published on or after the international filing date | "Y" | document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art |
| "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) | "&" | document member of the same patent family |
| "O" document referring to an oral disclosure, use, exhibition or other means | | |
| "P" document published prior to the international filing date but later than the priority date claimed | | |

Date of the actual completion of the international search
22 FEBRUARY 2000Date of mailing of the international search report
21 MAR 2000Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231
Facsimile No. (703) 305-3230Authorized officer
CHARLES MARMOR, II
Telephone No. (703) 305-3521

THIS PAGE BLANK (USPTO)

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

BLACK BORDERS

IMAGE CUT OFF AT TOP, BOTTOM OR SIDES

FADED TEXT OR DRAWING

BLURRED OR ILLEGIBLE TEXT OR DRAWING

SKEWED/SLANTED IMAGES

COLOR OR BLACK AND WHITE PHOTOGRAPHS

GRAY SCALE DOCUMENTS

LINES OR MARKS ON ORIGINAL DOCUMENT

REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY

OTHER: _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.

THIS PAGE BLANK (USPTO)